UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 13, 2004

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 71661-1, Surfacine® All-Purpose Cleaner, DP Barcode: 300179

From: Tajah Blackburn, Ph.D., Microbiologist
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Product Science Branch
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Thru: for Nancy Whyte, Team Leader
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To: Adam Heyward PM34/Sherri Gray
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Applicant: Intelligent Biocide LLC
One Industrial Way
Tyngsboro, MA 01879

Formulation From Label:

Active Ingredient(s)	% by wt.
Silver	0.0095%
Poly (hexamethylene biguanide) hydrochloride	0.5600%
Other Ingredient(s)	99.4305%
Total	100.0000%

I BACKGROUND

The product, Surfacine® All-Purpose Cleaner (EPA Reg. No. 71661-1) is a registered disinfectant for use on hard, non-porous surfaces in household, institutional, animal care, hospital, and medical environments. The applicant requested to amend the registration to include an alternate formulation. Studies were conducted by Lonza Global Technology Center located at 79 Route 22 East, Annandale, NJ 08801.

The data package contained a letter to the Agency, EPA form 8570-4, EPA form 8570-1, three studies (MRID No. 461954-01 thorough 461954-03), Statement of No Data Confidentiality Claims for all three studies, and the last accepted label.

II USE DIRECTIONS

The product is designed for use as a disinfectant on hard, non-porous surfaces such as appliances, bathroom fixtures, bathtubs, cabinets, cages, chairs, countertops, desks, doorknobs, floors, garbage cans, highchairs, kennel runs, microwave ovens, outdoor furniture, refrigerators, showers, sinks, stoves, tables, telephones, toilet bowl surfaces, urinals, and walls located in bathrooms, kitchens, dental/medical offices, hospitals, nursing homes, athletic facilities, barber shops, colleges, correctional facilities, dressing rooms, institutional facilities, factories, hotels, locker rooms, motels, prisons, public facilities, schools, salons, campgrounds, animal laboratories, kennels, pet shops, zoos, airplanes, boats, buses, campers, emergency vehicles, mobile homes, ships, trailers, trains, and taxis.

The proposed label directions provided the following information regarding the use of the product as a disinfectant: Pre-clean surface. Spray 6-8 inches from surface until thoroughly wet. Surface must remain wet for 10 minutes before wiping dry. Rinse food contact surfaces such as counter tops, tables, picnic tables, appliances and / or stove tops with potable water prior to reuse. Do not use on glasses, dishes, or utensils.

Note– Finally, the proposed label directions note that: "This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that . . ."

III AGENCY STANDARD FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital and Medical Environments

Under certain circumstances, previously submitted efficacy data is permitted to support an application or amendment for registration of a product. Only minimal confirmatory efficacy data is needed to demonstrate production of an effective formulation. In this case, the use solution for the new product is similar to the use solution for the product already registered. Confirmatory data must be developed on the applicant's finished product. For hospital disinfectants, 10 carriers on each of 2 samples representing 2 different batches of product must be tested against *Salmonella choleraesuis* (ATCC 10708), *Staphylococcus aureus* (ATCC

6538), and Pseudomonas aeruginosa (ATCC 15442), using either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products Test as Disinfectants Method. Killing on all carriers is required. The above Agency standards are presented in DIS/TSS-5.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID No. 461954-01 "AOAC Germicidal Spray Method" for Surfacine® All-Purpose Cleaner, by Nancy Sleightholm. Study conducted at Lonza Global Technology Center. Study completion date– October 20, 2003.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). Two lots (Lot Nos. 130091 and 130092) of the product were tested using the AOAC Germicidal Spray Method as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. The product was received ready-to-use. Fetal bovine serum was added to the test culture to achieve 5% organic soil load. Ten glass carriers were inoculated with 10 µL of 48 hour test culture and dried for 40 minutes at 36°C. Post-drying, the carriers were individually sprayed with 3 pumps of the test product at a distance of 6-8 inches. The carriers remained in contact with the test product for 1 minute at 22°C. The active ingredient was neutralized, by transferring each carrier to Letheen broth, with 7% Polysorbate 80 and 1% lecithin, at 30 second intervals. The subculture tubes were incubated for 48 hours at 36°C. Following incubation, the tubes were observed for the presence of visible growth. Controls included purity, sterility, viability, neutralization confirmation, and dried carrier counts.

Note– According to the applicant's comments, "The non-clinical laboratory study referenced in (the) report was conducted in compliance with the requirements of FIFRA Good Laboratory Practices Standards (40 CFR Part 160) except for: The stability of the test substance was not determined (40 CFR Part 160.105).

Note– Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

2. MRID No. 461954-02 "AOAC Germicidal Spray Method" for Surfacine® All-Purpose Cleaner, by Nancy Sleightholm. Study conducted at– Lonza Global Technology Center. Study completion date– October 20, 2003.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). Two lots (Lot Nos. 130091 and 130092) of the product were tested using the AOAC Germicidal Spray Method as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. The product was received ready-to-use. Fetal bovine serum was added to the test culture to achieve 5% organic soil load. Ten glass carriers were inoculated with 10 µL of 50 hour test culture and dried for 40 minutes at 36°C. Post-drying, the carriers were individually sprayed with 3 pumps of the test product at a distance of 6-8 inches. The carriers remained in contact with the test product for 1 minute at 22°C. The active ingredient was neutralized, by transferring each

carrier to Letheen broth, with 7% Polysorbate 80 and 1% lecithin, at 30 second intervals. The subculture tubes were incubated for 48 hours at 36°C. Following incubation, the tubes were observed for the presence of visible growth. Controls included purity, sterility, viability, neutralization confirmation, and dried carrier counts.

Note– According to the applicant's comments, "The non-clinical laboratory study referenced in (the) report was conducted in compliance with the requirements of FIFRA Good Laboratory Practices Standards (40 CFR Part 160) except for: The stability of the test substance was not determined (40 CFR Part 160.105).

3. MRID No. 461954-03 "AOAC Germicidal Spray Method" for Surfacine® All-Purpose Cleaner, by Nancy Sleightholm. Study conducted at– Lonza Global Technology Center. Study completion date– October 20, 2003.

This study was conducted against *Salmonella choleraesuis* (ATCC 10708). Two lots (Lot Nos. 130091 and 130092) of the product were tested using the AOAC Germicidal Spray Method as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. The product was received ready-to-use. Fetal bovine serum was added to the test culture to achieve 5% organic soil load. Ten glass carriers were inoculated with 10 µL of 50 hour test culture and dried for 40 minutes at 36°C. Post-drying, the carriers were individually sprayed with 3 pumps of the test product at a distance of 6-8 inches. The carriers remained in contact with the test product for 1 minute at 22°C. The active ingredient was neutralized, by transferring each carrier to Letheen broth, with 7% Polysorbate 80 and 1% lecithin, at 30 second intervals. The subculture tubes were incubated for 48 hours at 36°C. Following incubation, the tubes were observed for the presence of visible growth. Controls included purity, sterility, viability, neutralization confirmation, and dried carrier counts.

Note– According to the applicant's comments, "The non-clinical laboratory study referenced in (the) report was conducted in compliance with the requirements of FIFRA Good Laboratory Practices Standards (40 CFR Part 160) except for: The stability of the test substance was not determined (40 CFR Part 160.105).

V RESULTS

MRID No	Test Organism	Lot No.	Carrier Control	Number of Carriers	
				Exposed	Showing Growth
461954-01	*Staphylococcus aureus*	130091	6.5×10^4	10	0
		130092	5.7×10^4	10	0
461954-02	*Pseudomonas aeruginosa*	130091	5.7×10^4	10	0
		130092	7.5×10^4	10	0
461954-03	*Salmonella choleraesuis*	130091	3.0×10^4	10	0
		130092	2.2×10^4	10	0

VI CONCLUSIONS

1. The submitted efficacy data support the use of the product, Surfacine® All Purpose Cleaner, Alternate formula 2, as a disinfectant against the following microorganisms on hard, non-porous surfaces for a contact time of 1 minute in the presence of 5% organic soil load:

Staphylococcus aureus	MRID No. 461954-01
Pseudomonas aeruginosa	MRID No. 461954-02
Salmonella choleraesuis	MRID No. 461954-03

No growth was observed in the subcultures of the carriers tested against the required number of product lots. According to the laboratory reports, "data measurements. . . were within acceptance criteria." Dried carrier counts were at least 10^4. Neutralization confirmation testing showed positive growth of the organisms. Viability controls were positive for growth. The purity controls were pure. Sterility controls did not show growth.

VII RECOMMENDATIONS

1. The submitted efficacy label claims are acceptable regarding the use of the product, Surfacine® All Purpose Cleaner, as a disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of 5% organic soil load for a contact time of 1 minute:

Staphylococcus aureus	MRID No. 461954-01
Pseudomonas aeruginosa	MRID No. 461954-02
Salmonella choleraesuis	MRID No. 461954-03

2. On page 2 of the submitted label following *Trichophyton mentagrophytes*, the statement in parenthesis should state "a causative agent of Athlete's Foot Fungus."

3. On page 3 of the submitted label, in the heading "Types of Surfaces", for listing including appliances, microwave ovens, and refrigerators, this should be corrected to state "appliance exteriors", "exterior of microwave ovens", and "refrigerator exteriors".

4. Remove highchairs from the list of items that can be disinfected. Highchair table tops are considered food contact surfaces.